



Critical Values

Entire Laboratory Team

transition

Pursuing
Patient-Centered
Advocacy 6

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Laboratory Medicine Best Practices
Initiative Progress Report



Field Technical Service IT Laboratory Automation Customer Technical Support

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About Critical Values

transition



Mark H. Stoler, MD, FASCP

n 2008–2009, I headed the ASCP Task Force on Transition. The task force was charged with reenvisioning the overall strategic direction of ASCP in light of two trends: (1) the rapidly changing environment in which pathology and laboratory medicine operate, and (2) the pending retirement of ASCP Executive Vice President John R. Ball, MD, JD, FASCP. Dr. Ball will retire October 31, 2010, and a search for his successor is under way.

The task force identified four themes that will determine the direction of the Society and the profession for the foreseeable future. The next Executive Vice President must be capable of leading the Society in this direction. The four themes are as follows:

- What ASCP members want most is respect—from their peers, their colleagues in health care, their patients, and the public—for their role in health care. ASCP can provide the leadership to help members become indispensable partners in patient care and win that respect.
- ASCP must be customer-driven—*customer* is broadly defined as not only members but also other health professionals, patients, the public, and the public
- ASCP must be patient-centered—an advocate for the public health. In this paradigm, think of the letters **ASCP** as standing for Advocating for Society by Caring for Patients.
- ASCP must build on its strengths, namely, its emphasis on education, certification, and advocacy; the size and diversity of its membership; and the high quality of its programs.

This issue of Critical Values explores these themes from different perspectives. In my President's Message, I discuss the implications of a patient-centered approach to everything ASCP does. Junell M. Petersen, MS, MLS(ASCP)^{CM}SH^{CM}, chair of the Council of Laboratory Professionals, writes about the strength of ASCP at the grass-roots level. The co-chairs of the Resident Council address the tools residents need to make the transition from residents to fellows and from fellows to attending physicians.

Changes in the practice of pathology and laboratory medicine practice may be imposed from the outside or directed from within. An informed membership is best prepared to direct such changes from within. Articles in this issue address short-, medium-, and long-term issues that members should be aware of and should weigh in on. One short-term issue is regulation of laboratory-developed tests. The Food and Drug Administration regulates these tests as medical devices but is under pressure from the laboratory industry to regulate them under the Clinical Laboratory Improvement Amendments. The debate goes on.

Perhaps a medium-term issue is a process to identify evidence-based best practices for laboratory medicine. The Centers for Disease Control and Prevention Division of Laboratory Systems needs help from the laboratory community. This is prime time to make a contribution that will have a significant impact on laboratory service to improve patient care.

For the long term, Congress appropriated \$1.1 billion in 2009 to conduct "research that compares the clinical outcomes, effectiveness, and appropriateness of items, services, and procedures that are used to prevent, diagnose, or treat diseases, disorders, and other health conditions." The goal of comparative effectiveness research is to identify the best health care practices. Pathology and laboratory medicine must become involved in this research. An excerpt from the Institute of Medicine's 2009 report on comparative effectiveness research, including some priority topics, is published here.

In light of the health care reform debate, Corinne Fantz, PhD, DABCC, of Emory University shares her suggestions for evaluating critical values to save time and money while maintaining high-quality patient care. Finally, in light of the outbreak of swine flu, artist Luke Jerram presents an alternative view of the H1N1 virus—through glass.

I look forward to your feedback about this issue of Critical Values. Send your comments to ascp@ascp.org and put "Critical Values" in the subject line. Education and training of pathologists and laboratory professionals will be the theme of the April 2010 issue, so watch for it.

Dr. Stoler is president of ASCP.

Critical Values

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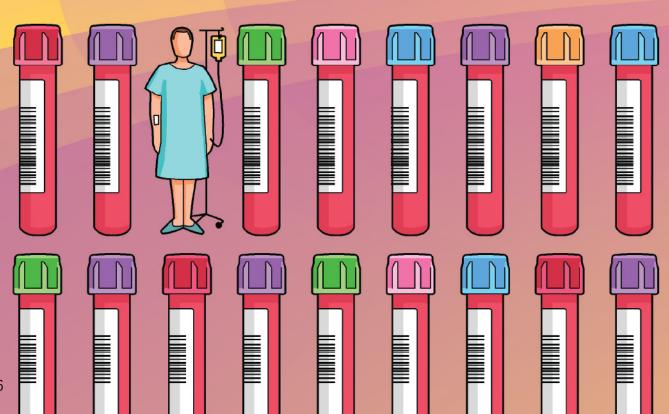
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Patient-Cen



Leadership Messages Message from the President





C . . 1 . . .

red Advocacy By Mark H. Stoler, MD, FASCP

Many people adopt New Year's resolutions in hopes of making positive changes in their lives. However, most fail to follow through, and few achieve any lasting change. The ASCP leadership team is determined this will not happen to ASCP as it embarks on a journey of transition designed to strengthen the Society and the profession.

The journey began in 2006 with formation of a task force charged with looking at the future of pathology and laboratory medicine. The work was continued by a second task force in 2007. In 2008, I chaired the Task Force on Transition, which was charged with helping the Society find a new strategic direction—one that will enable ASCP, its members, and the profession make the transition to the new reality of medical practice.

The Driving Force for Change

In my October 2009 message, I provided a general overview of the task force's recommendations. This column discusses one of these recommendations, specifically, the fact that patient-centered advocacy should drive all decision making at ASCP.

Advocacy refers not only to the Society's government relations activities but also to a fundamental shift in how pathologists and laboratory professionals think and work. Henceforward, we must examine every decision through the lens of what is best for the patient and society as a whole. Before we plan a meeting, develop a course, or take a position, we must evaluate the effect of our decision on patients and their overall welfare. We must not simply consider the medical consequences, we must consider other factors, such as the impact on health care costs and patient access. We must do this even when the decision conflicts with our personal or professional goals.

Optimized Patient Care

In general, ASCP has been good about advocating on behalf of patients, but now we must become more global. We must begin making decisions that optimize medical care so patients get the tests and treatments they need when they need them without having to undergo unnecessary medical procedures.

One approach is to reexamine and streamline testing protocols using the best available medical evidence. For example, women younger than 21 are at extremely low risk for cervical cancer. Therefore, do they really need an annual Pap test? Do they truly need to be screened at all?

Evolving guidelines for molecular (DNA) tests for the human papillomavirus (HPV) recommend that young women forgo routine HPV DNA testing. However, many laboratories overutilize these tests, sometimes even performing them on teenagers.

In contrast, best evidence suggests that women older than 30 should have both a Pap and an HPV test as a more accurate way to screen for cervical cancer.^{2,3} If both tests are negative, patients usually need not be screened again for three years. Unless other risk factors exist, more frequent testing is wasteful and potentially harmful.

With the current emphasis on optimizing patient care, as pathologists and laboratory professionals we should be the key source of information about laboratory testing and should help patients and clinicians benefit from our knowledge. We must make ourselves more accessible to clinicians in order to provide expertise on which tests to do and when to do them. Our concerted efforts to promote good relationships with clinicians so they can provide better care to their patients is what patient-centered advocacy is all about. No one is in a better position to help eliminate unnecessary testing and expense than pathologists. And given the ongoing expansion of knowledge and test complexity, the more generalist the physician, the more he or she will need our expertise.

Beyond the Status Quo

This expanded focus for our profession is, in the opinion of the task force and ASCP leadership, key to the survival, relevance, and prosperity of our profession. It won't happen overnight. ASCP must promote a philosophy of patient-centric care among its members. Furthermore, all its programs and efforts must evolve so that members can acquire the knowledge and skills they need to thrive in an evolving health care environment.

Abandoning the status quo and pursuing a strategy of patient-centered advocacy and optimized care may sometimes appear contrary to our own interests. But the status quo cannot continue. Just listen to the news. Economic pressures and the push for health care reform will ultimately force change. Right now we have a chance to do it right, but we must be willing to bring ourselves to the table and participate in the process. Otherwise, decisions will be made without our input, as numerous other specialists are ready and willing to take our place.



Federal legislators are seeking ways to save money on health care, but they cannot do it well without the help of laboratory organizations like ASCP. Everyone in the profession needs to come together and participate. As the largest organization and one that is open to cooperation and collaboration, we will command attention and can have a significant impact—especially with your involvement. The survival and vitality of our profession depend on it.

In closing, you can use **ASCP** as an acronym to help you remember this message and the important concept it conveys: **A** stands for *advocacy*, **S** for *society*, **C** for *care*, and **P** for *patients*. We must *advocate* for our *Society* (and for the broader *society*) by striving to provide optimized *care* that centers on the needs of *patients*. I invite your ideas and comments. Send an e-mail to me at President@ascp.org.

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Leadership Messages

Message from the Chair of the Council of Laboratory Professionals



Petersen

THE ROOTS OF ASCP

By Junell M. Petersen, MS, MLS(ASCP)^{CM}SH^{CM}

The phrase "strengthening our grass roots" turns up often and in several different contexts—not only within ASCP but also within many professional organizations. According to dictionary.com, one definition of grass roots is "pertaining to or involving the common people." The term common people is not a phrase I would use to describe the laboratory team: the laboratory professionals, pathologists, and residents who are ASCP. However, the word root is defined as "the fundamental or essential part," as in "the root of the matter." I believe the word root provides an excellent description of the many people who volunteer at ASCP.

In my last message ("The Unseen Quality of ASCP," Critical Values, October 2009, Vol. 2, Issue 4, pp. 9–10), I described the ASCP Council of Laboratory Professionals (CLP) and the role it plays within the organization. The Council represents all laboratory professionals, except pathologists and residents, and is responsible for keeping the ASCP Board of Directors apprised of their needs and concerns. A vital part of the Council—what I like to think of as the root of the organization—is the group of volunteers called Local Representatives.

Qualities of a Good Local Representative

Local Representatives are responsible for promoting the laboratory profession and ASCP within their local laboratories and communities. However, this is really just the tip of the iceberg. Because they serve on the frontline where they can keep their fingers on the pulse of the membership, Local Representatives are a vital communications link between the grass-roots membership and ASCP. Without their assistance, it would be much more difficult for ASCP to provide for the needs of its members and advocate on their behalf.

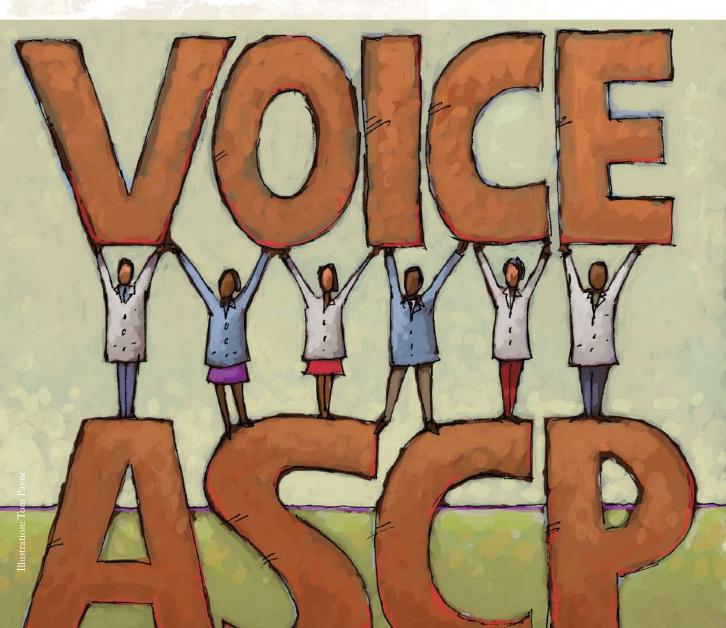
What exactly does it take to be a Local Representative? Why should anyone want to be one? I'll address the why question first. If you want to become more active in ASCP, this is an excellent way to get started. It is often a stepping stone to other volunteer opportunities at the regional and national levels. If you think your local community needs more networking and educational opportunities for laboratory professionals, serving as a Local Representative

is a good way to make this happen. It is also an excellent way to network with other laboratory professionals while promoting and enhancing your profession.

Second, being a Local Representative is not difficult, but certain personal qualities and characteristics usually make the job easier and more enjoyable. Local Representatives need not be social butterflies, but they should be reasonably outgoing and have the ability to communicate well with people at all levels of ASCP and within their communities. They should have a genuine concern for the laboratory profession and the patients it serves, and they should enjoy being involved and knowing what is happening within the profession. Networking and organizational skills are extremely important.

Some Specific Responsibilities

The following is an action plan for Local Representatives that summarizes their primary duties and responsibilities. You don't have to do everything on the list. You need to be a good communicator. After that, you can select those skills that fit you.



 Be a good communicator. Set up a communications network and an e-mail address group comprising laboratory professionals from a variety of hospitals,



ASCP Council of Laboratory Professionals

Front row left to right: Teresa Y. Harris, MT(ASCP)SBB; M. Sue Zaleski, MA, SCT(ASCP)HT; Manuela Sawalha, MHS, MT(ASCP); Cynthia S. Parrish, MBA, MLS(ASCP)^{CM}SC,SH,DLM

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Not Pictured: Barbara L. Burch, MT(ASCP); Barbara S. Caldwell, MS, MT(ASCP)SH^{CM}; Christina P. Nickel, MHA, MT(ASCP)

physician's offices, and private laboratories in your area—and individuals who are willing to forward any information you send them on to other laboratory professionals in their network.

- Become familiar with key legislative issues at the state and national levels. ASCP helps you do this by providing several online resources: the ASCP e-Advocacy Center, e-Policy News, and Action Alerts.
- Serve as a resource person for your area. For example, be prepared to answer questions about ASCP membership and its benefits. Help people get connected by encouraging experienced staff to serve as mentors for newer technicians or students interested in the field. Develop a relationship with local news reporters and newscasters, and help them get the technical information and background they need for local news stories about laboratory testing.
- Seek opportunities to raise awareness about the

laboratory profession among educators, young people, and the general public in your community, and participate, whenever possible, in recruitment opportunities.

- Organize local educational programs and networking opportunities for laboratory professionals in your area.
- Collaborate whenever possible with laboratory professionals from other facilities and professional organizations; this will help conserve resources and avoid duplication of efforts. Mutual cooperation on the local level also helps build relationships and promotes collaboration on state and national programs and activities.

ASCP is involved in many activities that affect the profession. For example, the ASCP Washington office works with legislators to help improve health care legislation, and the global efforts of ASCP have affected many Third World countries. ASCP members have also met with numerous state and local officials to detail the workforce problems of the laboratory profession. Information on the many different activities ASCP is involved in is sent to Local Representatives to be relayed to ASCP members and other laboratory professionals in their area.

For more information about becoming a Local Representative, contact Betty Sanders, ASCP Program Manager, Membership Councils, at betty.sanders@ascp.org or your regional representative. The list of ASCP Local Representatives, organized by region, can be found at www.ascp.org/LocalReps. If you have any other comments, questions, or suggestions, please send an e-mail to me at MemberChair@ascp.org.

Ms. Petersen is the Outreach Coordinator for Laboratory Services at Rice Memorial Hospital, Willmar, MN.

<u>eadership Messages</u> Message from the Co-chairs of the Resident Council



Huppmann

Bollinger

very July 1, residency programs undergo a period of transition during which students become residents, residents become fellows, and fellows become attendings. Whether you are simply moving from your second to third year of residency or moving across the country to start a fellowship, change can be difficult, especially when budgets are tight. With this in mind, the Resident Council offers some programs that can help.

Resident Subspecialty Grants

One of the most important programs is the Resident Subspecialty Grant Program. A total of \$22,000 is awarded each year to help residents defray the cost of doing elective rotations at outside institutions. These grants allow them to gain increased exposure to areas of pathology of particular interest to them and broaden their training experience by exposing them to material unavailable at their own institutions. It also gives them an opportunity to work with prominent pathologists of their own choosing.

In 2009, ASCP began offering two rounds of subspecialty grants. Last October, the Society awarded a total of \$10,000 to five residents, representing the first round of grants. The deadline for applications for the second round of grants is January 15, 2010. Recipients will be announced at the Resident Council reception on March 21 during the United States and Canadian Academy of Pathology (USCAP) meeting in Washington, D.C.

Rotations vary in length from two to four weeks. Each grant recipient receives a \$1,000 or \$2,000 stipend, depending on the length of study. All ASCP resident members in their first to third years of training may apply. Recipients are selected on the basis of their financial need and their strong interest in a specific subspecialty training program. For more information or to submit an application, visit www.ascp.org/grants.



TOUS for Transition

By Alison R. Huppmann, MD, FASCP, and Thomas J. Bollinger, MD, MPH, FASCP



"Day on the Hill" Grant

Residents who have an interest in the political process and in advocating on behalf of pathology and laboratory medicine can spend a day with lawmakers discussing pathology-related issues. The Hill Day Grant Program was created to provide an opportunity for residents to participate in the ASCP "Day on the Hill" in Washington, D.C., April 18-20, 2010.

In 2009, two residents attended Hill Day with the help of these grants. They also took part in an educational session on legislative advocacy. The organizational structure of congressional offices, committees, and staff was covered, along with a review of effective presentation techniques. Recipients of the 2010 Hill Day Grants will also take part in this very useful training session.

All ASCP resident members in their first to fourth years of training are eligible to apply for Hill Day Grants. Recipients receive round-trip airfare or appropriate mileage compensation, hotel accommodations for two nights, and up to \$250 for additional expenses. For more details, go to www.ascp.org/grants. The application deadline is February 3. Grant recipients will be announced at the ASCP Resident Reception at the USCAP meeting on March 21.

Educational Opportunities

Also coming up this year are several educational courses for pathologists, which offer quality instruction and a great opportunity for residents to meet top specialists in the field. Residents can take these courses for half the regular price, or they can attend for free on a standby basis. Residents who choose the standby option simply sign up and wait to see whether there are any unfilled course openings. Residents are notified of acceptance 72 hours before the conference begins so they can make arrangements to attend. In general, the standby option works best if the course is being offered locally or if transportation is not an issue.

The first course in the 2010 lineup is "Gynecologic Pathology: A Practical Surgical and Cytologic Perspective." The course, which is being taught by Steven G. Silverberg, MD, FASCP, will be held February 2–6, in Tucson, Arizona. Details on this and other educational courses are available on the ASCP Web site, at www.ascp.org/ASCPStore/Store/MeetingsConferences/Pathologist.aspx.

As the new year gets under way, we are hopeful that many ASCP resident members will take advantage of one or more of these opportunities. We also want to encourage residents to consider getting more involved in ASCP. Volunteer opportunities abound, and they are a great way to network and meet fellow colleagues. They also offer invaluable experience that will carry over into future careers. For more information about volunteer positions or to sign up, contact Betty Sanders at betty.sanders@ascp.org.

Happy New Year! We wish you the best for 2010 and look forward to seeing you at the USCAP meeting in March. Send your comments, questions, or suggestions to ResidentCouncil@ascp.org.

Dr. Huppman is a Fellow in Pediatric Pathology at Children's Hospital of Philadelphia, Philadelphia, PA. Dr. Bollinger is a Hematopathology Fellow in the Department of Laboratory Medicine and Pathology at the University of Minnesota, Minneapolis, MN.





Initial National Priorities for Comparative Effectiveness Research

Editor's Note: This article is an excerpt from the summary of the consensus report Initial National Priorities for Comparative Effectiveness Research, prepared by the Committee on Comparative Effectiveness Research Prioritization, Board on Health Care Services, Institute of Medicine of the National Academies, and released on June 30, 2009. This excerpt is reprinted with permission from the National Academies Press, Copyright 2009.

Background

oday, when a patient and physician, perhaps with other L clinicians and family caregivers, are discussing the best course of treatment for the patient's medical condition, they often do not have the scientific evidence they need to make a determination. Although there may be studies that indicate that a treatment is efficacious relative to a placebo, there frequently are no studies that directly compare the different available alternatives or that have examined their impacts in populations of the same age, sex, and ethnicity or with the same comorbidities as the patient. Comparative effectiveness research (CER) is designed to fill this knowledge gap. CER focuses attention on the evidence base to assist patients and health care providers across diverse health settings in making more informed decisions. They will need useful, practical information concerning the most effective interventions and health care services for their particular situation.

To help identify which health care services work best, Congress, in the American Recovery and Reinvestment Act (ARRA) of 2009 (P.L. 111-5), appropriated \$1.1 billion as a down payment to provide strong federal support of CER. This provision in the law reflected the legislators' belief that better decisions about the use of health care resources could improve the public's health and reduce the costs of care. According to the legislation, CER covers "research that compares the clinical outcomes, effectiveness, and appropriateness of items, services, and procedures that are used to prevent, diagnose, or treat diseases, disorders, and other health conditions." The law appropriated \$400 million to the National Institutes of Health (NIH), \$300 million to the Agency for Healthcare Research and Quality (AHRQ), and the remaining \$400 million to the

Secretary of Health and Human Services (HHS). The purposes of the appropriations were, according to the language of the law:

- "to evaluate the relative effectiveness of different health care services and treatment options" and
- "to encourage the development and use of clinical registries, clinical data networks, and other forms of electronic data to generate outcomes data."

The law also charged the Institute of Medicine (IOM) to form a consensus committee and solicit stakeholder input to recommend national priorities for spending the \$400 million designated for the Secretary. The legislation imposed a short time frame on this study—the IOM report deadline of June 30, 2009, was 19 weeks after the president signed the legislation into law. The IOM President's Fund generously supported the study process until the study's sponsor, AHRQ, could contract with the IOM; IOM funds entirely paid for the public questionnaire and its analysis. The Robert Wood Johnson Foundation also contributed significantly to this study. This support permitted the IOM to rapidly establish a committee and to commence work. The committee encompassed a broad range of expertise, perspectives, and experience, including members who work with consumers and patients, in clinical care and research, or in health care and government administration.

The committee's principal task was to prepare a list of priorities for CER funding; most of its time was spent developing a process for priority setting, eliciting a wide array of input from the public, and deliberating over a list of nominated research topics. Then, as the complexities of priority setting for CER became apparent, the committee began to outline the development of an infrastructure that

would sustain a long-term, national CER effort. The committee provided recommendations to implement that infrastructure required for a sustained CER effort. The main justification for including economic considerations is that the overall value of a strategy can be understood best by considering costs and

benefits together. In such a circumstance, value may be judged from the perspective of the patient, provider, or payer. Many stakeholders thought CER might persuade payers to support or improve reimbursement for particular services, but the committee did not discuss leveraging research findings to payment policy.

[The report then lists the committee's 100 recommendations for priority CER topics. The following is a sampling of those topics.]

- Compare the effectiveness of genetic and biomarker testing and usual care in preventing and treating breast, colorectal, prostate, lung, and ovarian
 - cancer, and possibly other clinical conditions for which promising biomarkers exist.
- Compare the effectiveness of various screening, prophylaxis, and treatment interventions in eradicating methicillin-resistant Staphylococcus aureus (MRSA) in communities, institutions, and hospitals.
- Compare the effectiveness of different strategies of introducing biologics into the treatment algorithm for inflammatory diseases, including Crohn's disease, ulcerative colitis, rheumatoid arthritis, and psoriatic arthritis.
- Compare the effectiveness of management strategies for localized prostate cancer (e.g., active surveillance, radical prostatectomy [conventional, robotic, and laparoscopic], and radiotherapy [conformal, brachytherapy, proton-beam, and intensity-modulated radiotherapy]) on survival, recurrence, side effects, quality of life, and costs.
- Compare the effectiveness of management strategies for ductal carcinoma in situ.
- Compare the effectiveness of treatment strategies for atrial fibrillation including surgery, catheter ablation, and pharmacologic treatment.
- Compare the effectiveness and costs of alternative

detection and management strategies (e.g., pharmacologic treatment, social/family support, combined pharmacologic and social/family support) for dementia in community-dwelling individuals and their caregivers.



- Compare the effectiveness of interventions (e.g., community-based multilevel interventions, simple health education, usual care) to reduce health disparities in cardiovascular disease, diabetes, cancer, musculoskeletal diseases, and birth outcomes.
- Compare the effectiveness of imaging technologies in diagnosing, staging, and monitoring patients with cancer including positron emission tomography (PET), magnetic resonance imaging (MRI), and computed tomography (CT).
- Compare the effectiveness of comprehensive care coordination programs, such as the medical home, and usual care in managing children and adults with severe chronic disease, especially in populations with known health disparities.

Defining Comparative Effectiveness Research

An agreed-upon definition of CER is an essential first step for setting priorities and developing a sustainable national CER Program. It informs the public of the focus of this research and its importance in their lives, and it informs investigators of the characteristics of the research to be supported by CER funds. It provides a basis for judging research proposals to perform CER and for evaluating the impact of that research and the success

of a national CER Program. In formulating its definition, this committee drew upon definitions by several government agencies and other IOM committees (see Chapter 2):

Comparative effectiveness research (CER) is the generation and synthesis of evidence that compares the benefits and harms of alternative methods to prevent, diagnose, treat, and monitor a clinical condition or to improve the delivery of care. The purpose of CER is to assist consumers, clinicians, purchasers, and policy makers to make informed decisions that will improve health care at both the individual and population levels.

Recommendations for a Robust National CER Enterprise

Based on stakeholder input and its own deliberations, the committee concluded that the country needs a robust CER infrastructure—referred to throughout as the "CER Program"—to sustain CER well into the future, including carrying out the research recommended in this report and studying new topics identified by future priority

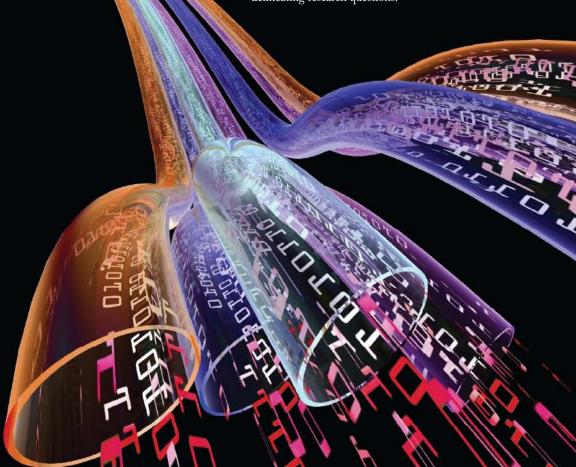
setting. The

committee's list of 100 priority topics responds to the requirements of ARRA to advise the Secretary on how to distribute CER funds from the bill. In addition, the list could be useful beyond the \$400 million appropriated to the Secretary by influencing the distribution of funds by NIH, AHRQ, and other agencies that fund CER. The list is not sufficient, however, to ensure the needs of a future in which new interventions and new diseases will mandate new priorities for CER. The committee's examination of previous priority-setting efforts and its study of the nominated research topics conveyed through its questionnaire led it to conclude that CER must be an ongoing process.

Health care is dynamic; new diseases and health needs can arise suddenly and other health problems might become insignificant when a treatment is found. As new CER produces new evidence and closes gaps in evidence, CER might need to take new directions. A continuous process is necessary to update funding priorities as conditions change and the impact of previous CER becomes evident.

Recommendation 1: Prioritization of CER topics should be a sustained and continuous process, recognizing the dynamic state of disease, interventions, and public concern.

Recommendation 2: Public (including consumers, patients, and caregivers) participation in the priority-setting process is imperative to provide transparency in the process and input to delineating research questions.



Recommendation 3: Consideration of CER topics requires the development of robust, consistent topic briefs providing background information, current practice, and research status of the condition and its interventions.

Recommendation 4: Regular reporting of the activities and recommendations of the prioritizing body is necessary to evaluate the portfolio's distribution, its impact for discovery, and its translation into clinical care in order to provide a process for continuous quality improvement.

Recommendation 5: The HHS Secretary should establish a mechanism—such as a coordinating advisory body—with the mandate to strategize, organize, monitor, evaluate and report on the implementation and impact of the CER Program.

Recommendation 6:

- The CER Program should fully involve consumers, patients, and caregivers in key aspects of CER, including strategic planning, priority setting, research proposal development, peer review, and dissemination.
- The CER Program should develop strategies to reach out to, engage, support, educate, and, as necessary, prepare consumers, patients, and caregivers for leadership roles in these activities.
- The CER Program should also encourage broad participation in CER in order to create a representative evidence base that could help identify health disparities and inform decisions by patients in special population groups.

Recommendation 7: The CER Program should devote sufficient resources to research and innovation in the methods of CER, including the development of methodological guidance for CER study design such as the appropriate use of observational data and more informative, practical, and efficient clinical trials.

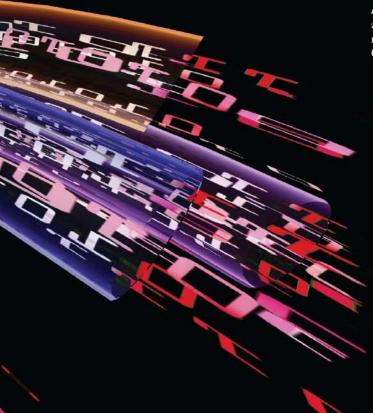
Recommendation 8:

- The CER Program should help to develop large-scale, clinical and administrative data networks to facilitate better use of data and more efficient ways to collect new data to inform CER.
- The CER Program should ensure that CER researchers and institutions consistently adhere to best practices to protect privacy and maintain security.
- The CER Program should support the development of methodologies for linking patient-level data from multiple sources.
- The CER Program should encourage data holders to participate in CER and provide incentives for cooperation and maintaining data quality.

Recommendation 9: The CER Program should develop and support the workforce for CER to ensure the nation's capacity to carry out the CER mission. Important next steps include:

- 1. Development of a strategic plan for research workforce development.
- Long-term, sufficient funding for early career development including expanding grants for graduate and postgraduate training opportunities in comparative effectiveness methods as well as career development grants and mid-career merit awards.

Recommendation 10: The CER Program should promote rapid adoption of CER findings and conduct research to identify the most effective strategies for disseminating new and existing CER findings to health care professionals, consumers, patients, and caregivers and for helping them to implement these results in daily clinical practice.



The full report is available at www.iom.edu/en/Reports/2009/ ComparativeEffectivenessResearchPriorities.



Epner

Laboratory Medicine Best Practices:

A Progress Report

By Paul L. Epner, MBA, MEd

In June 2003, a paper by McGlynn et al. in the *New England Journal of Medicine* made headlines when it reported that adults in 12 metropolitan areas, on average, received appropriate care only 54.9% of the time. For many, the thought of such a high level of inappropriate care was astounding. Less often questioned was the methodology for determining appropriate care. Determining what's *right* in health care has been and continues to be a source of debate. The response to this study and others was an increased focus on the existence of evidence (or the lack thereof) to guide clinician judgment.

The earliest use of the phrase "evidence-based medicine" (EBM) may have been by McMaster University in 1992, long before the McGlynn study caused some to ask, "What's right?" A few years later, Sacket and Rosenberg defined five characteristics necessary for the utilization of EBM: "(i) convert information needs into answerable questions; (ii) track down, with maximum efficiency, the best evidence with which to answer them; (iii) critically appraise that evidence performance for its validity (closeness to the truth) and usefulness (clinical applicability); (iv) apply the results of this appraisal in clinical practice; and (v) evaluate performance."

Although EBM has increasingly become part of the health care landscape, there has not been a broad, consistent approach to evidence review in laboratory medicine. To address this issue, the Centers for Disease Control and Prevention (CDC), through its Division of Laboratory Systems (DLS), committed to organizing a national effort to support the development of a systematic, evidence-based process to identify best practices in laboratory medicine. DLS initially is focused on the pre- and postanalytical phases of the total testing process because nearly two-thirds of errors occur in those phases.

Phase 1. Development of Systematic Review Methods

In October 2006 the CDC convened a multidisciplinary panel, the Laboratory Medicine Best Practices (LMBP) Workgroup. The primary goal of Phase 1 was to develop systematic and transparent methods for evaluating evidence and then demonstrate their usefulness in a "proof-of-concept"

application. After considerable effort to define terms, methods for systematic review and evaluation, and criteria for making recommendations, a methodology was established. In addition, key elements include presentation of summary evidence review results in a compact and effective format.

For the initial proof-of-concept phase, the topic selected was patient specimen identification. A number of challenges presented themselves during this phase, including a lack of peer-reviewed, published, and accessible literature. The application of the newly developed systematic review methods to the limited quantity and quality of available evidence resulted in the conclusion that the evidence was insufficient for each candidate practice evaluated, and the Workgroup was unable to make any recommendations for or against these practices. Subsequently, the Workgroup determined that waiting for the published literature to emerge was an unacceptable strategy. Instead, it recommended seeking additional nontraditional sources of evidence through outreach to health care organizations. A complete report of Phase 1 can be found at the project Web site, www.futurelabmedicine.org.

Phase 2. Pilot-Testing

During Phase 2, the CDC and Battelle Memorial Institute Project Team and the Workgroup continued to evolve the systematic review and recommendation methods, and initiated an effort to collect nontraditional (unpublished) evidence. This phase involved an initial pilot test of the methods with unpublished submissions associated with seven practices in two topic areas: patient specimen identification and communication of critical values.

The collection of unpublished data occurred through an outreach effort to a limited number of health care organizations. In order to minimize the burden, they were asked to submit only evidence for which data had already been collected. Furthermore, sites recruited were given assurances of anonymity if they desired. Methods developed were to be applied to standards for evidence reviews in the same manner for published or unpublished evidence.

Phase 2 ended without recommendations for or against the candidate practices from either topic area. In the time allotted for this phase, it was not possible to adequately augment the published evidence with enough data from unpublished sources to support evidence-based best practice recommendations. Nonetheless, the Project Team and Workgroup concluded that expanding the effort to procure unpublished studies that could be included in evidence reviews beyond this initial effort was warranted.

Phase 3. Pilot Expansion with Unpublished Data

As a result of Phase 2 outcomes, a more formal effort was made to create an effective network that would identify sites with relevant retrospective data. A network administrator was identified, and a concerted outreach to laboratory professional organizations was conducted to expand the awareness of the project. (ASCP was one of the organizations that responded to CDC's inquiry and has provided valuable support for the effort.) The pilot-testing continued with a third topic area added to the previous two, *blood culture contamination*. Additionally, a new interactive data submission form for use by organizations submitting unpublished data was developed.

As in the previous phases, an initial step in the evidence review process is selecting candidate practices. A total of eight practices were identified, criteria developed, and literature searches conducted, and a call for submission of unpublished data was made through publications, e-mails, and announcements at meetings. For *each* of the eight practices being studied and following a short informal assessment of the suitability of their data, three to nine sites were invited to submit data.

In September and October, project personnel reviewed, abstracted, and synthesized all the available evidence using their review methods to produce standardized evidence summaries for each practice with information related to each study's quality and practice effect size (or impact). Consistent with the LMBP project's review methods, during November, expert panels for each topic area were to meet to evaluate the evidence summaries, effect sizes, and consistency of the evidence and then draft the results of the evidence review and an evidence-based recommendation about the adoption of each practice. Finally, in December, the Workgroup, acting as the pilot test recommending body, was to convene to consider the draft recommendations.

Conclusions

At the time this article is being written (early November 2009), the third phase of the LMBP project is still in progress. Whether recommendations will be forthcoming for any of the candidate practices reviewed in any of the three topic areas cannot yet be determined. However, two observations can be made:

- Published literature on laboratory practices is limited and typically focuses on the utility of particular assays. In particular, there is a shortage of welldesigned studies in peer-reviewed literature that focus on pre- and postanalytical phases of the total testing process.
- 2. On the basis of limited telephone interviews and data reviews, it appears that health systems routinely make implementation decisions about new practices without sufficient evidence to determine whether they will have a positive impact on patient care.

Laboratory professionals are asked to become involved in the LMBP project through generating evidence and utilizing project recommendations in decision making, as follows:

- Register at www.futurelabmedicine.org to be informed about new calls for evidence and about practice recommendations issued.
- 2. Submit suggestions at the Web site for topics for

- which systematic evidence reviews could identify laboratory medicine practices likely to produce improved patient care.
- 3. Attend educational sessions on the skills and competencies needed to strengthen the quality of evidence available for study. Educational sessions will be announced through the project's Web site as well as through network partners.

Optimum outcomes for many patients depend on obtaining the right laboratory result at the right time. Identifying best practices to improve the total testing process is one way that the pathology and laboratory medicine profession can help deliver the best patient care.

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Mr. Epner is a healthcare strategy consultant in Evanston, IL, and Network Administrator for the Laboratory Medicine Best Practices (LMBP) project under a contract to Battelle Centers for Public Health Research. Assistance in preparing this article was provided by Susan R. Snyder, PhD, MBA, Senior Economist in the Division of Laboratory Systems, National Center for Preparedness, Detection, and Control of Infectious Diseases, Centers for Disease Control and Prevention in Atlanta, GA, and LMBP Initiative Director, and Edward Liebow, PhD, Director of the Battelle Centers for Public Health Research and Evaluation in Seattle, and LMBP Project Manager.



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Transition

Lab-Developed By Ellen J. Sullivan, MSJ Tests

. ..

Regulation of laboratory-developed tests (LDTs) remains a controversial issue for both regulators and industry.

The Food and Drug Administration (FDA) views LDTs as medical devices and regulates them as such, said Don St. Pierre, deputy director of the FDA Office of In Vitro Diagnostic Device Evaluation and Safety. St. Pierre spoke at the Lab Institute 2009 conference, presented by Washington G-2 Reports in September in Washington, D.C.

In contrast, David Mongillo, vice president for policy and medical affairs at the American Clinical Laboratory Association, asserted at the conference that LDTs are not medical devices and therefore should be regulated under the Clinical Laboratory Improvement Amendments (CLIA), rather than by the FDA.

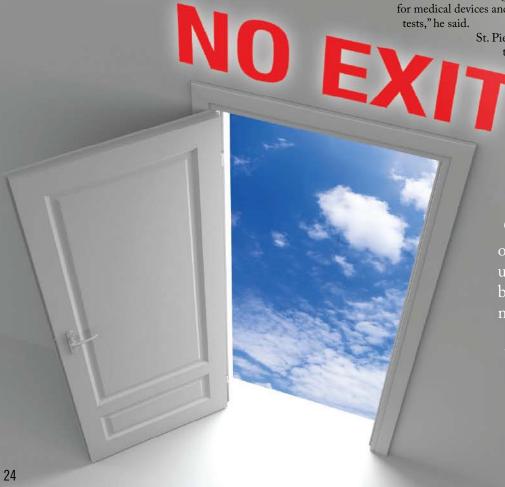
"We need two regulatory separate pathways: one for medical devices and one for laboratory-developed tests." he said.

St. Pierre said the agency is concerned that molecular-diagnostic tests

are reliable, and that their value and limitations are understood. The developers must establish the validity of the tests, he added.

Test kits distributed outside the lab should undergo FDA review, but some LDTs enter the market without review.

-- Don St. Pierre, Food and Drug Administration



UNDER SCRUTINY

"Test kits distributed outside the lab should undergo FDA review, but some LDTs enter the market without review," St. Pierre said. "The problem is that people are going outside the original intent of the regulation."

St. Pierre indicated that a change in FDA policy is a possibility, but added, "This is not going to be solved tomorrow. I guarantee it."

In September, ASCP weighed in with comments on the definition of LDTs to the Agency for Healthcare Research and Quality (AHRQ) Technology Assessment Program. ASCP's comments were a response to the July 24, 2009, draft technology assessment, "Quality, Regulation and Clinical Utility of Laboratory-developed Tests," conducted by the ECRI Institute Evidence-based Practice Center and issued by AHRQ at the request of the Coverage and Analysis Group at the Centers for Medicare and Medicaid Services (CMS).

ASCP commended CMS and AHRQ for their efforts to establish a measure of quality for LDTs.

"ASCP is pleased that the document attempts to clearly define the term 'molecular genetic test' through descriptions of the assays, specific examples and their intended diagnostic purpose," said then-ASCP President Barbara J. McKenna, MD, FASCP. ASCP further agreed that evaluation of laboratory-developed molecular tests should include the test's analytic and clinical validity, but cautioned that clinical utility remains a subjective standard that depends on how clinicians use assay results to manage patient treatment, not on an objective quality inherent in

"Requiring complete proof of clinical utility as a prerequisite for marketing of these assays might impede or even prevent patient access to them," ASCP asserted. "A lengthy approval process that requires definitive evidence of clinical utility might hinder the development of these assays, preventing American researchers from implementing

the test method.

translational findings

into clinical practice."

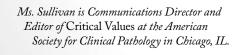
ASCP President Mark H. Stoler, MD, FASCP, added that evidence of clinical validity is the key to offering patients tests that are truly useful and not wasteful of valuable health care resources. "Striking the proper balance is one of the major conundrums of our rapidly evolving times," he said.

Also in September, the College of American Pathologists announced its recommendations for strengthening oversight of LDTs. The recommendation calls for "a three-tier, riskbased system that would protect patients by ensuring every

> LDT is reported to one or another oversight bodies depending on where a test is placed in a graduated system of review based on the test's potential risk to patients."1

Reference

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ASCP Board of Certification Makes the Transition

he new ASCP Board of Certification (BOC) opened for business on October 23, 2009, a result of the unification of the ASCP Board of Registry (BOR) and the former National Credentialing Agency for Laboratory Professionals (NCA). The first BOC examinations were administered on October 24.

"Transitions can be challenging, but the BOR and NCA worked hard to make it go as smoothly as possible for all laboratory professionals—those who are certified and those who are seeking certification," said Kathleen Becan-McBride, EdD, MLS(ASCP)^{CM}, chair of the ASCP BOC Board of Governors.

Under the BOR, Dr. McBride's credential, MT(ASCP)^{CM}, reflected the fact that she was a certified medical technologist who had completed certification maintenance. Under the BOC, her new credential is MLS(ASCP)^{CM}, reflecting the new designation of medical laboratory scientist (MLS) and her completion of the certification maintenance program. Individuals previously holding the CLS(NCA) certification will also hold the MLS(ASCP)^{CM} designation.

The designation for individuals certified as clinical laboratory technicians or medical laboratory technicians is MLT(ASCP). The BOC also offers a Technologist in Cytogenetics, or CG(ASCP), credential and a Molecular Biologist, or MB(ASCP), credential. Most other credential designations will remain the same.

All BOR and NCA credentials that were active and current as of October 23, 2009, will be transferred to the ASCP BOC. These individuals do not have to take an examination. "Active and current" refers to anyone who has documented continuing education activities in medical laboratory science over the past three years and has submitted those activities for certification maintenance through the ASCP BOC or previously with the NCA.

Medical technologists certified by the ASCP BOR before 2004 are not required to participate in certification maintenance. However, if they do not, their credential will remain MT(ASCP). If and when they complete a certification maintenance program, their credential will change to MLS(ASCP)^{CM}. Approved continuing education credits from any organization can be used to fulfill the BOC recertification.

Previous NCA certificants due to recertify in February 2010 may submit recertification documentation on schedule to the BOC. The BOC will honor all contact hours earned by previous NCA certificants.

Questions? Go to www.ascp.org or call BOC Customer Service at (800) 267-2727, option 2.



2009 ASCP Masterships

Honor distinguished ASCP members who have made significant contributions to the field of pathology and laboratory medicine and to ASCP:



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William (Jack) Frable, MD, MASCP



Raymond Gambino, MD, MASCP



David W. Glenn, MASCP, MLS(ASCP)CM



Carol A. Gomes, MS, MASCP, MT(ASCP), HTL, DLM, CPHQ, FACHE



Richard L. Kempson, MD, MASCP

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Recognizes an outstanding ASCP volunteer who has gone above and beyond his or her duties and performed outstanding service for the Society:



Michael D. Feldman, MD, PhD, FASCP

2009 ASCP Awards

Ward Burdick Award for Distinguished Service to Pathology



Jay M. McDonald, MD, FASCP

H.P. Smith Award for Distinguished Pathology Educator



Richard Mac DeMay, MD, FASCP

Israel Davidsohn Award for Distinguished Service



Fred H. Rodriguez, Jr., MD, FASCP

Philip Levine Award for Outstanding Research



Arul M. Chinnaiyan, MD, PhD, FASCP

ASCP on Health Care Reform

ASCP worked feverishly in 2009 to ensure that pathology's voice in health care reform proposals on Capitol Hill was heard. Overall ASCP has been supportive of health care reform efforts on Capitol Hill but did not endorse the overall packages that were moving through the House and the Senate. As a patient-centric organization, ASCP believes it is important that pathology and laboratory services are available to all of the nation's patients. The Society adopted health care reform as one of its top public policy priorities in 2008 and in 2009. Throughout 2008–2009 ASCP and its members advocated policies that would provide the nation's patients with access to high-quality pathology and laboratory services.

Pathology is a service, not a commodity, and ASCP advocated to include provisions in both the House and the Senate legislation that would close the loopholes on physician self-referral that have been created by the In-Office Ancillary Service Exception (IOAS) under the Stark law. Unfortunately, the efforts to close the Stark IOAS exceptions were not included in health care reform legislation, but ASCP's efforts on this issue will continue.

ASCP also worked with the medical community to pass a fix to the Sustainable Growth Rate (SGR) Formula under Medicare. ASCP did endorse H.R. 3961, the "Medicare Physician Payment Reform Act," which will replace the physician payment system that is widely acknowledged to be dysfunctional and that continually threatens access to care for elderly and disabled patients. A fix to the SGR would also provide physician practices with financial stability and predictability and enable them to invest in the infrastructure needed to build a health care system for the 21st century. Without Medicare physician payment reform, the goals of health system reform will remain out of reach.

In September, ASCP and the pathology community successfully removed a Senate Finance Committee provision that would have implemented a 20% co-pay on Medicare-covered lab tests and a tax on all clinical laboratory and pathology revenue. Over 2,500 letters were sent through the ASCP e-Advocacy Center in a 48-hour period to defeat the proposed co-pay.

However, as of early November 2009, both House and Senate reform bills included proposals to reduce the annual adjustment to the clinical laboratory fee schedule (CLFS) by an amount equivalent to the estimated annual increase in productivity, as determined by the U.S. Department of Labor. Historically, such estimates have averaged about 1.4%. In addition, the Senate version imposes a 1.75% reduction in the CLFS, also effective in 2011. This reduction would increase to 1.95% in 2015 to pay for a partial, temporary change to the current prohibition on direct reimbursement of tests ordered within 14 days of a patient discharge from a hospital. The bill also extends the provision allowing for technical component billing by independent laboratories performing services for Medicare inpatients and "reasonable reimbursement" for laboratory services provided at small rural hospitals. There is also a provision calling on the Centers for Medicare and Medicaid Services to submit a report to Congress outlining recommendations for legislative and administrative actions to reform the reimbursement mechanisms for new clinical laboratory tests.

ASCP Health Care Reform Resources: www.ascp.org/Health-Care-Reform#Resources

Motion to Dismiss Lawsuit Challenging Gene Patents Denied

A federal district judge has denied Myriad Genetics' motion to dismiss the lawsuit opposing patents on the BRCA1 and BRCA2 genes, whose mutations are associated with an increased hereditary risk of breast and ovarian cancer. ASCP is a plaintiff in the lawsuit, brought by the American Civil Liberties Union against Myriad and the U.S. Patent and Trademark Office. "The widespread use of gene sequence information as the foundation for biomedical research means that resolution of these issues will have far-reaching implications, not only for gene-based health care and the health of millions of women facing the specter of breast cancer, but also for the future course of biomedical research," said Judge Robert W. Sweet of the U.S. District Court of the Southern District of New York in his ruling denying the motion (www.ascp.org/Newsroom). At the ASCP Annual Meeting in October, Chicago-based writer and film producer Joanna Rudnick shared clips of her movie, "In the Family," in which she documents her personal experience of testing positive for the BRCA genetic mutation at the age of 27. The film explores issues of family history, genetic testing, surgical options, and her opposition to gene patents (http://inthefamily.kartemquin.com).

Hill Day Grants for Residents

ASCP is offering an opportunity for two residents to participate in the legislative process on Capitol Hill. Residents who have an interest in the political process and pathology-related issues are encouraged to apply for a grant for the 2010 event, which will be held April 18–20. The application deadline is February 3. For more information and an application, contact Betty Sanders, ASCP Program Manager, Membership Councils, at betty.sanders@ascp.org.

Two New Books from ASCP Press

ASCP Press released two new books in October: *Practical Diagnosis of Hematologic Disorders*, 5th edition, which is fully compliant with the new 2008 World Health Organziation (WHO) classification changes and brings more than 100 new molecular tests into the text; and *Integrated Hematopathology: Morphology and Flow Cytometry Immunophenotyping with IHC*, which uses a problem-based teaching method to demonstrate the integration of morphology with FCI findings, enhanced as useful by immunohistochemistry. The text is 2008 WHO classification-compliant.

ASCP Transition Resources

Online Learning

ASCP offers a variety of online opportunities to earn continuing medical laboratory education credits for institutional, relicensure, and certification maintenance requirements. Options available on an ongoing basis include On-demand Webcasts, Histology Online, eCourses, and Online Case Studies. For details, visit www.ascp.org/eLearning.

eCourses

- 1. An Overview of Chemical Terrorism Agents
- 2. Confessions of a Laboratory Safety Officer
- 3. Preparing for Large Scale Emergencies and How Your Terrorism Preparedness Training Can Help

- 4. Sample Collection and Anticipated Clinical Sample Flow Following a Chemical Exposure Incident
- 5. Specimen Collection, Storage, and Packaging
- Preventing Errors in the Hematology Laboratory to Improve Patient Safety

On-demand Webcasts

- 1. Update on the Use of Pap Tests and Human Papillomavirus Testing
- 2. Revisiting Repair on Gynecology Samples
- Biomarkers of Stroke—Current Status and Future Promise
- 4. Understanding the Cost of Quality
- Swine Flu: Testing the Lab Response to an Epidemic— Now and a Glimpse of Possibilities

- 6. The Reference Range Revolution—What is Driving All the Changes?
- 7. Hemoglobin A1C Issues and Opportunities
- 8. Error Management in the Cytopathology Laboratory: Learning from Our Mistakes
- Learning from Our Mistakes: A Variety of Diagnostic Pitfalls in Gynecologic Cytopathology
- Maximizing Employee Performance: The Art of the Relationship
- Quality Control Do's and Don'ts in Pathology Laboratories
- 12. Case Studies from the Pediatric Hematology Laboratory
- Pre-analytical Variables in the Coagulation Laboratory— New CLSI Guidelines
- Molecular Diagnostics in the Community Hospital Setting
- Phlebotomy A to Z: Using Critical Thinking and Making Ethical Decisions
- 16. The Positive Direct Antiglobulin Test—Where Do We Go from Here?

Teleconferences

ASCP teleconferences offer a convenient and cost-effective way for laboratories to offer programs for their entire staff. The following is a list of upcoming programs. For details, visit www. ascp.org/Teleconferences.

March 9: Elutions: Applications, Methods, and Clinical Relevance

March 10: Challenges and Opportunities in Detecting Prescription Drug Use and Abuse

March 16: Laboratory Identification of Antiphospholipid Antibodies

March 19: Histology Process Improvement—Worklo

March 19: Histology Process Improvement—Workload Recording

March 23: Leukocyte Microchimerism Following Blood Transfusion

March 24: Business Process Mapping Workshop

March 25: Pediatric Bone Marrow Morphology

March 26: Blood Cultures: A Primer of Essentials

March 30: Diagnosing Factor Deficiencies in the Coagulation Laboratory: A Case Study Approach

March 31: Laboratory Diagnosis of Celiac Disease

April 1: Molecular Diagnostics and Targeted Therapy for Colorectal Carcinoma

April 2: Standard of Care in Liver Biopsy Evaluation: What Is It and How Can It Be Used To Optimize Liver Biopsy Reporting?

April 6: Improving Patient Safety in Surgical Pathology

April 7: A Passion for Challenge

April 8: Diagnosing Thyroid Follicular Lesions on FNA Biopsy: How Helpful Are New Immunocytochemical Markers?

April 13: Continued Importance of Blood Lactate

Measurements in Critical Care

April 16: Well-Differentiated Lipomatous Tumors: A Common and Challenging Problem to the Practicing Pathologist

April 20: Laboratory Testing in Hepatitis Syndromes: A Widening Spectrum

April 21: Pathology: Error Reduction in an Error-Prone Environment

April 22: Lung and Mediastinal Fine-Needle Aspiration Cytology—Newer Perspectives

April 27: Age-Specific Care for Phlebotomy

April 28: Essential Components of a Successful Method Evaluation Experience

April 29: Molecular Diagnostics of Thyroid Cancer

April 30: Liquid Gold: Review and Update of Routine Urinalysis

Pathologists Note

The Maintenance of Certification (MOC) process adopted by the American Board of Pathology (ABP) encompasses a set of requirements that must be fulfilled every 10 years following certification. As of January. 1, 2006, all primary and subspecialty certificates issued by ABP expire on the last date of the 10-year anniversary of their issuance. Specific deadlines must be met at two-year intervals. Total requirements must be fulfilled within 10 years. ASCP is offering 263 Self-Assessment Module (SAM) credits in 2009, assessment programs to meet MOC Part IV (Evaluation of Performance in Practice), and tools for tracking MOC credits.

Laboratory Professionals Note

Individuals who become certified by the ASCP Board of Registry in 2004 and beyond are required to maintain their certification through the ASCP Board of Certification Certification Maintenance Program (CMP) every three years.

www.ascp.org/education





Arts in Culture

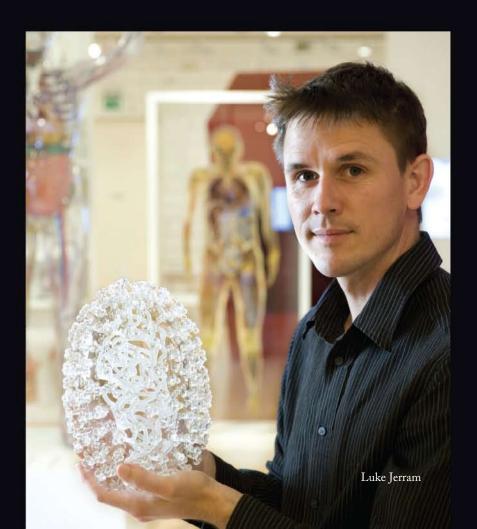


H11N1 in Glass

A rtist Luke Jerram of Bristol, United Kingdom, created this glass sculpture of the H1N1 virus to contemplate the global impact of the disease and to explore the tension between the beauty of the virus as artwork and its impact on humanity. The sculpture was recently acquired by the Wellcome Collection of London and is on temporary display in the "Medicine and Art" exhibition at the Mori Art Museum in Tokyo through February 28, 2010.

"Luke Jerram's work brings us an intriguing and visually stunning physical representation of the H1N1 virus," said Clare Matterson, Wellcome Trust Director of Medicine, Society and History. "It offers us a point of departure to explore the impact such viruses have had on populations and to find out more about the global research to tackle them."

www.lukejerram.com/projects/glass_microbiology www.wellcomecollection.org www.mori.art.museum/eng



A Critical Values

News for the Entire Laboratory Team



Fantz

Strategies for Evaluating Critical Value Limits:

Opportunities for Saving Time and Money Without Compromising By Corinne Fantz, PhD, DABCC

It has been a few years since the Joint Commission added the communication and monitoring of critical values piece to the National Patient Safety Goals. As the requirements become more demanding, strategies for being more efficient without compromising care are increasingly valuable. In this article I highlight opportunities for saving both time and money.

The Value of the Clinical Laboratory

Most of the published literature on critical values is in the form of hospital surveys. ^{1,2} While there is clearly some value in comparisons with other hospitals, there is no standard of care. What one hospital considers life-threatening may be completely different in another setting. For example, a cancer center may have a more liberal approach to defining a low white count (in patients receiving chemotherapy) than a community hospital, which would typically consider a low white count an unexpected result and more likely a critical situation. Many of these surveys mix centers of different sizes, complexity of patients, and, importantly, little to no information about the instrumentation used. This complicates the matter further, so these surveys are probably best at offering a *ballpark estimate* of how one hospital compares with another.

There are examples of institutional case studies that allow comparisons with similar practices.³ For example, an academic medical center may want to compare its practice to that of the Massachusetts General case study. If the center is similar in size and scope, this report may be a good starting point for



benchmarking practices for critical value reporting. When Emory Medical Laboratories updated its list, we aligned our hematocrit with that of other academic medical centers and had it approved by the medical practice committee. This change reduced the number of calls for critical hematocrits from 318 per week to about 57 per week. Making similar changes with six other high-volume analytes decreased our call volume by half. Surveys exist for Veterans Health Administration hospitals and pediatric institutions as well.⁴

For outcomes, evidence for setting critical value parameters is limited. 5-7 What these few analytespecific studies do offer are valuable glimpses into the impact on patient care; however, these come with a few caveats. These studies have focused on current practices, such as analyzing outcomes of patients with results above and below a particular cutoff. There is an inherent bias if physicians are already being called at a defined limit. It therefore may be difficult to discern whether a patient is treated more or less aggressively based on receiving a call versus an arbitrary cutoff used in the study design.

Regulators have left it up to hospitals to define their critical value lists. Most have followed the advice of Emancipator and relied on the input of the physician practice group. This group has the clinical expertise and typically represents the institution's diverse group of physicians. They can comment on specific clinical needs like special programs, say, a transplant group, a cancer center, or an emergency department.

They also are the group that understands the resources and limitations of the system. The value in this approach is developing a list with the clinician's perspective. A word of caution, however, *critical* can become courtesy.

Perhaps the best strategy for determining critical cutoffs is to use all available data. Compare your laboratory with your peers, both nationally and locally. Surveys available in the literature can provide a start, but pick up the phone and call the laboratory down the street. Physicians are not always practicing at one unique location; if your list is widely different

from another local laboratory, you are probably going to hear about it. Additionally, it is important to seek clinical input. But do your homework before meeting with the medical practice committee. Find out what your peers are doing. Talk to the high-profile service groups at your institution.

As noted, critical values are more or less agreed upon by consensus. There is no standard list that everyone can follow for every situation. In setting limits, look at peer, local, and national data but also consider the method used. When setting critical limits, review the analyte in your proficiency data to determine the variation at a specific level among the various manufacturers. Analysis of these data may demonstrate that a potassium of 3.0 mmol/L can be range from 2.9 to 3.2 mmol/L, but a PT of 40 seconds may range from 24 to 59 seconds depending on the method.9

While it may not be possible to standardize individual analytes, it is certainly possible to standardize reporting



templates. This makes the data easier to search and sort. The table below shows a couple of example templates that we use when making critical value calls. When we don't reach anyone on the first call, we use the second template. These templates can be helpful in providing cost estimates of the labor spent by documenting the time it takes to reach a provider.

What if you can't reach a provider? If you don't already have one in place, define a clear escalation policy. If a technologist is making the initial call and he or she has difficulty locating a provider, consider forwarding the call to a laboratory customer service representative. He or she can be extremely helpful and often has increased resources for locating clinicians; this can save technologist time. Use on-call physicians, and, even better, identify a central call number for outpatients. The drawback is that these procedures are often difficult to implement because they require constant updating and system cooperation, so the support of the medical practice groups is needed.

To ensure the best care for patients, if a covering physician or other responsible provider cannot be identified, close the loop with a phone call to the patient. Remember, if your list represents true critical values, the patient is in a *life-threatening situation and something can be done about it.*

Strategies for Improving Processes

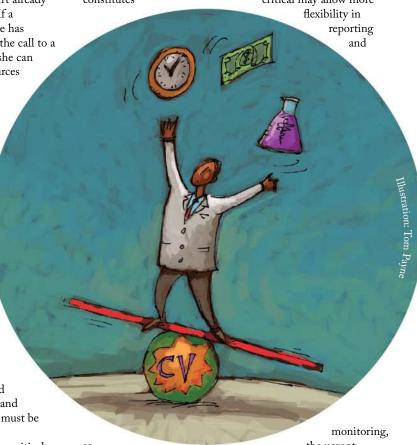
There is always a balance between helping to alert someone to a life-threatening situation and slowing down care with increased documentation and a high background of unnecessary calling. The list must be appropriate for the practice.

Consider how often you call. Do you call every critical result? Are there opportunities for decreasing call volume by limiting the calls to once a day or week for the same critical analyte? Does your system allow for trending data? Can your alert system identify a bad trend before it actually becomes critical? At Emory Medical Laboratories, we are looking at rules that would fire on discharge to review a patient's status by trending the most recent lab tests. While the absolute number may not be critical, the data over time may clearly show a trend that would otherwise go undetected at discharge.

Trends can be subcategorized as intelligent rules for alerts. Creatinine rules are often difficult because above 2 or 3, there is chronic failure and an absolute cutoff would be a great deal of background noise for very little gain. What you really want to be alerted to is an acute change that may otherwise go undetected, for example, a creatinine change of 0.61 to 1.43 mg/dL. Hospital information systems that could follow an individual patient's trend would be extremely valuable if they could be reviewed during the stay and also checked at discharge with built-in alerts recognizing significant changes.

What about communicating information that the physician needs to know about but maybe not urgently? A different classification scheme may be necessary for test

results that are significant but perhaps not life-threatening or for which an intervention is not possible. Some institutions may refer to these as courtesy calls, while others may redefine a separate time interval for result reporting and refer to a different tier of alert: red (urgent/life threatening), orange (semiurgent), and yellow (important). Redefining what constitutes critical may allow more



results communicated.

the urgent can be more effectively

Autoverification is supposed to help with the rapid release of results. Typically, when an instrument produces a critical result, that result goes to middleware to be held until review and verification. In this day and age, with the shortage of medical technologists in the laboratories, they are asked to do more with less. Automation and autoverification seem to mitigate this situation, but when the technologist is busy multitasking, he or she may not see a pending result. It is possible then that critical and arguably more important results may take longer to report if they are flagged as critical.¹⁰ This is not at all what clinicians want. Middleware software should be flexible enough not only to satisfy the needs of the regulatory agencies but also to provide timely results to clinicians. Electronic alerts are increasingly being used to improve the effectiveness of communication and will likely continue to do so.11,12

Proper communication and documentation of critical values/critical tests are important for patient safety and have gained the attention of regulatory agencies. Decreasing the number of calls made, either by aligning lists with peers,

developing strategies to limit calling to "red alerts" only, or calling only the first critical result (for selected analytes) are all ways in which laboratories have improved these processes and saved both time and money. In the future, automated/electronic alerts and intelligent rules will continue to improve these processes further, perhaps by identifying patients at risk before they even become critical.

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Critical results called to and read back by _	Date Time by lab personnel
Attempted to call critical result to @	Date Time by lab personnel

Strategies for Improving Processes

- 1. Implement processes to appropriately flag results that fall outside the analytic measurement range (with mixed alpha and numeric response) and all critical test results.
- 2. Invest in middleware that allows for more flexible ways to track required documentation.
- 3. Incorporate new tests/services as they become relevant.
- 4. Set turnaround time limits by using the 90th or 95th percentile to look for outliers, not the mean.

Opportunities for Saving Time and Money

- 1. Design clear, well-thought-out escalation policies for both inpatient and outpatient areas.
- 2. Reserve critical values calls for tests for which the specimen integrity is not in question.
- 3. Design your lists to reflect only life-threatening results that can be acted upon.
- 4. Monitor processes and address gaps in care that lead to lengthy delays.



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